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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,959	02/26/2002	Seah H. Lim	010.00131	5006

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EXAMINER
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UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/082,959

Applicant(s)

LIM ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 01 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

1. The Amendment filed July 1, 2005 in response to the Office Action of February 28, 2005 is acknowledged and has been entered. Previously pending claims 1-5 and 7-17 have been cancelled. Claim 6 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

***Claim Rejections - 35 USC 112***

4. Claim 6 remains rejected under 35 USC 112. second paragraph for the reasons previously set forth in the paper mailed February 28, 2005, Section 5, page 4.

Applicant argues that the designation SP-17 for the particular antigen of the invention is known to those of skill in the art as detailed by the cloning and sequencing reported in Lea et al, IDS item and further, the amino acid sequence for the molecule is recorded as Accession No. Q15506 in the NCBI database, a copy of which is submitted. The arguments have been considered but have not been found persuasive, although Applicant refers to Lea et al in the Response as well as in the specification, the claimed antigen is not limited to the SP-17 of Lea et al. Further, it is noted that none of the references disclosed in the specification was incorporated by reference, therefore information in the Lea et al reference that might unambiguously define the claimed antigen would be considered new matter if the specification were amended to contain that information. Likewise, the specification does not recite Accession No. Q15506 and amendment of the specification to include this information would also be considered new matter. Applicant's arguments have not been found persuasive and the rejection is maintained.

*New Grounds of Rejection*

*Claim Rejections - 35 USC 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chiriva-Internati et al, Blood, 2000, 96:272b, of record in view of Lefkovits, Immunology Methods Manual. The Comprehensive Sourcebook of Techniques, Vol 3., 1997, pgs 1670-1673.

The claim is drawn to an isolated cytotoxic T cell which specifically recognizes Sp-17.

Lefkovits teaches conventional methods of producing cytotoxic T cells to protein antigens.

Chiriva-Internati et al specifically teach that Sp17 protein, although selective for expression in testis, is also expressed on the surface of multiple myeloma cells. The reference specifically teaches that Sp17 protein has been characterized in that both B and T cell epitopes have been defined. SP17 should be an idea target for immunotherapy of multiple myeloma. It is a suitable target for the treatment of multiple myeloma (see abstract). The reference teaches as set forth above but does not teach the production of cytotoxic T cells specific for SP17.

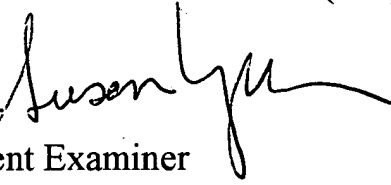
It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made cytotoxic T cells specific for SP17 using conventional methods of Lefkovits because Chiriva-Internati et al specifically teach that Sp17 protein has not only defined B cell but also T cell epitopes. One would have been motivated to make cytotoxic T-cells to Sp17 protein in order to make molecules useful for characterizing the effectiveness of said T cells for the treatment of multiple myeloma as suggested by Chiriva-Internati et al. One would have had a reasonable expectation of success in producing cytotoxic T-cells to Sp17 protein because Chiriva-Internati et al explicitly teaches that the protein comprises T cell epitopes and because of the conventional nature of the process of producing cytotoxic T-cells as taught by Lefkovits.

7. No claims allowed.

8. All other objections and rejections set forth in the prior Office Action are hereby withdrawn.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar   
Primary Patent Examiner  
September 19, 2005